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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,328	08/21/2003	Rodolfo R. Llinas	05986/100K521-US1	7569

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EXAMINER

NATNITHITHADHA, NAVIN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,328	Applicant(s) LLINAS, RODOLFO R.	
	Examiner Navin Natnithithadha	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-26, 28, 30 and 32-36 is/are rejected.
- 7) ☒ Claim(s) 5, 27, 29 and 31 is/are objected to.
- 8) ☒ Claim(s) 37 and 38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 1, 5, 10, and 18 have been amended. Claims 26-38 have been added. Claims 1-38 are pending.
2. The objection to claim 5 is WITHDRAWN in response to the Applicant's Amendment.

Response to Arguments

3. Applicant's arguments with respect to claims 1-4 and 6-25 have been considered but are moot in view of the new ground(s) of rejection.
4. Applicant's arguments with respect to 35 U.S.C. 112, first paragraph, rejections of claims 3, 4, 20, and 21 are persuasive, therefore, the rejections are WITHDRAWN.

Election/Restrictions

5. Newly submitted claims 37 and 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original claims 1-25 were directed to a method and apparatus for sensing the activity of neural tissue of the brain and stimulating the neural tissue. Support for this embodiment of the invention is given in the "Summary of the Invention" section of the Specification. New claims 37 and 38 are directed to a method and apparatus for sensing the activity of muscle tissue, which is a different type of tissue than neural

tissue and located in a different area of the body in regards to neural tissue. Therefore, claims 37 and 38 would be distinct from a method and apparatus for sensing the activity of neural tissue and would require a separate search in the art.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37 and 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 2, 10, 26, and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Corbett, III et al, US 5,515,848 A, in view of Corbett, III et al, US 5, 201,903 A.

Claim 10: Corbett '848 teaches a device for sensing the activity of neural tissue (see col. 1, lines 18-22), comprising: an electrode (microelectrode) 40 of "sufficiently small size" (see col. 1, lines 36-48), the electrode 40 being deployed in a blood vessel proximate to the neural tissue (implantable), wherein a signal on the electrode 40 is monitored (sensed) by way of a wire 74 connected to the electrode 40 (see col. 3, lines 1-3), the "signal being indicative of the electrical brain activity of the neural tissue" (see col. 1, lines 18-35). Corbett teaches the electrode 40 must be extremely small "in order

Art Unit: 3736

to isolate currents within small regions of living tissue", i.e. nerve cells (see col. 1, lines 37-41). Therefore, electrode 40 "would be of sufficiently small size such that it is capable of being inserted into a capillary". Corbett '848 does not explicitly teach a "catheter" and the electrode 40 "being deployed from the catheter". However, Corbett ,903 teaches that the "cable 42 can thus function as an extremely small catheter" (see col. 8, lines 8-9). It is clear that the cable 42 (referred to as conductor body) in Corbett '848 are equivalent structures and function as "an extremely small catheter". If the Applicant believes the conductor body 42 in Corbett '848 is not a sufficient in teaching of a "catheter", then it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett's invention to incorporate "an extremely small catheter" in order to provide implantation of the microelectrode device.

Claims 1 and 2: Corbett teaches the subject matter of the methods as claimed in the rejection of claim 10 above.

Claims 26 and 28: Cobett teaches the microelectrodes are used for electrical stimulation of nerves (see col. 3, lines 1-3).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 3736

7. Claims 2-4, 7, 8, 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A, as applied to claim 1 and 10 above, and further in view of Kovacs et al, US 5,883,603 A.

Claims 2-4, 7, 8, 11, 14, and 15: Corbett does not teach the subject matter as claimed. However, Kovacs teaches a device for sensing the activity of neural tissue (see col. 15, lines 50-57), comprising: a signal processor (control circuit) 36 being arranged in a catheter 148 (see fig. 12 and col. 16, line 4) and being coupled to a "plurality of electrodes" 130 and 132 (see fig. 10). The catheter 148 is capable of inserting electrodes into an artery at the position claimed in claims 3 and 4. In addition, Kovacs teaches electrodes 120 and 122 having different lengths (see fig. 10). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett invention to incorporate a signal processor and a plurality of electrodes in order to process the sensed neural activity for utilizing neural prosthesis (see Corbett, col. 1, lines 36-44).

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A in view of Kovacs et al, US 5,883,603 A, as applied to claim 11 above, and further in view of Hoek, US 6,615,067 B2.

Claims 12 and 13: Corbett does not teach the claimed subject matter. However, Kovacs teaches low-noise differential amplifiers (see col. 16, line 2). Kovacs does not teach a digital converter which includes a Schmitt trigger. However, use of a Schmitt trigger for converting analog signals to digital signals is well known in the art. For

Art Unit: 3736

example, Hoek teaches a Schmitt trigger 307 connected to a filter 306 (see col. 6, lines 24-29). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs circuitry to include a Schmitt trigger in order to have accurate digital processing of an electrode signal.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A in view of Kovacs et al, US 5,883,603 A, as applied to claim 15 above, and further in view of John, US 4,913,160 A.

Claim 16: Corbett does not teach the claimed subject matter. However, Kovacs teach low-noise differential amplifiers (see col. 16, line 2). Kovacs does not teach a plurality of digital converters and a multiplexer. However, digital processing of a plurality analog signals using digital converters and a multiplexer is well known in the art. For example, John teaches a plurality of electrode signals 11 amplified by amplifiers 14 that are inputted to an A/D converter/multiplexer 33, wherein the signals are process digitally by a microprocessor 35 (see fig. 1 and col. 4, lines 24-31). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs circuitry to include an A/D converter/multiplexer in order to have accurate digital processing of an electrode signal.

10. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A, in view of Corbett, III et al, US 5, 201,903 A, as applied to claim 1 above, and further in view of Lieber et al, US 2002/0117659 A1.

Art Unit: 3736

Claim 6: Corbett teaches microelectrodes and does not explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett's microelectrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A in view of Kovacs et al, US 5,883,603 A, and further in view of John, US 4,913,160 A, as applied to claim 16 above, and further in view of Lieber et al, US 2002/0117659 A1.

Claim 17: Corbett teaches microelectrodes but does not explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett's microelectrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A, in view of Corbett, III et al, US 5, 201,903 A, and further in

Art Unit: 3736

view of Lieber et al, US 2002/0117659 A1, as applied to claim 6 above, and further in view of Imram, US 5,391,147 A.

Claim 9: Corbett, Kovacs and Lieber do not teach a cup-like end to an electrode. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Kovacs's electrode to have a cup shaped end in order to accurately sense the activity of neural tissue.

13. Claims 18-21 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, in view of Corbett, III et al, US 5,515,848 A.

Claims 18 and 30: Schulman teaches a method of stimulating neural tissue (see col. 1, lines 11-16), comprising: placing an electrode 40' in a blood vessel; providing a signal on the electrode for stimulation (see col. 10, line 16 and claim 15). Schulman does not teach the "electrode being of sufficiently small size such that it is capable of being inserted into a capillary". However, Corbett '848 teaches a device for sensing the activity of neural tissue (see col. 1, lines 18-22), comprising: an electrode (microelectrode) 40 of "sufficiently small size" (see col. 1, lines 36-48), the electrode 40 being deployed in a blood vessel proximate to the neural tissue (implantable), wherein a signal on the electrode 40 is monitored (sensed) by way of a wire 74 connected to the electrode 40 (see col. 3, lines 1-3), the "signal being indicative of the electrical brain activity of the neural tissue" (see col. 1, lines 18-35). Corbett teaches the electrode 40

Art Unit: 3736

must be extremely small "in order to isolate currents within small regions of living tissue", i.e. nerve cells (see col. 1, lines 37-41). Therefore, electrode 40 "would be of sufficiently small size such that it is capable of being inserted into a capillary". It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schulman to have a microelectrode in order to place a stimulating/sensing electrode within the neurological anatomy of an animal or human patient (see Schulman, col. 1, lines 11-16).

Claim 19: Schulman teaches the electrode 40' being placed in the blood vessel (see fig. 2).

Claims 20 and 21: Schulman teaches placing an electrode 40' in a blood vessel, which inherently is capable of placing electrodes into a blood vessel at the position claimed.

14. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, in view of Corbett, III et al, US 5,515,848 A, as applied to claim 18 above, and further in view of Lieber et al, US 2002/0117659 A1.

Claim 22: Corbett teaches microelectrodes but does not explicitly teach nano-electrode(s) having a nano wire and a micro-wire. However, Lieber teaches nano-sensors comprising nano-electrodes 36 (see fig. 1a and paragraph 133) connected to nanowire 38 and electrical connections 22 (see fig. 1a and see paragraph 135). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett's microelectrodes in order to have electrodes that are of sufficient size to be placed near neural tissue.

15. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, in view of Corbett, III et al, US 5,515,848 A, as applied to claim 18 above, in view of Lieber et al, US 2002/0117659 A1, and further in view of Daniel et al, US 6,622,731 B2.

Claims 23 and 24: Schulman does not teach an array of nano-electrodes having different lengths. Lieber teaches nano-electrodes as discussed above for claim 22. Daniel teaches a catheter 198 comprising nerve stimulation electrodes 176 and 180 having different advancement lengths from catheter 198 (see col. 15, lines 21-26, and col. 29, lines 56-58). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schulman's device in order to effectively stimulate a tissue site or organ.

16. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al, US 5,651,767 A, in view of Corbett, III et al, US 5,515,848 A, and further in view of Lieber et al, US 2002/0117659 A1, as applied to claim 22 above, and further in view of Imram, US 5,391,147 A.

Claim 25: Schulman, Corbett, and Lieber do not teach a cup-like end to an electrode. However, a cup-like end to an electrode is a well-known structure to electrodes. For example, Imram teaches a catheter comprising an electrode 221 having a cup shaped end (see fig. 19 and col. 8, lines 47-52). It would have been obvious for

one of ordinary skill in the art at the time the invention was made to modify Schulman's electrode to have a cup shaped end in order to properly stimulate neural tissue.

17. Claims 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett, III et al, US 5,515,848 A, as applied to claim 1 above, and further in view of Rise, US 6,374,140 B1.

Claims 32-36: Corbett does not teach the claimed subject matter. However, the claimed subject matter relates well known electrode signal processing techniques in the art. For example, Rise teaches a device, comprising: a sensor 20 with an electrode for measuring electrical activity of the brain, a signal processor 30 including a filter 200 for filtering the signal received from the electrode (see col. 5, lines 24-34). The signal processor 30 performs extraction and pattern recognition of the signal to determine a brain state, ie. Seizure or normal brain activity (see col. 30-48). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Corbett invention to provide processing of the signal from the microelectrodes in order identify brain activity and detect seizure.

Allowable Subject Matter

18. Claims 5, 27, 29, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter:

As to claim 5, the prior art of record does not teach the method of claim 1, including monitoring a further signal on the further electrode after applying the stimulus to the neural tissue, and comparing the signal to the further signal.

As to claims 27 and 29, the prior art of record does not teach the method of claim 1 and the device of claim 10, including a second electrode being operative to provide a stimulation signal to the neural tissue and placed in a second blood vessel proximate to the neural tissue.

As to claim 31, the prior art of record does not teach the method of claim 18, including placing a second electrode in a second blood vessel proximate to the neural tissue, and providing a monitor signal to the second electrode.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the


Art Unit: 3736

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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22 July 2005


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